

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):



- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

(12) PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. AU 199853019 B2
(10) Patent No. 712236

(54) Title
A mask and a vent assembly therefor

(51)⁶ International Patent Classification(s)
A61M 016/06

(21) Application No: 199853019

(22) Application Date: 1998.02.09

(30) Priority Data

(31) Number	(32) Date	(33) Country
PO5045	1997.02.10	AU

(43) Publication Date : 1998.08.20

(43) Publication Journal Date : 1998.08.20

(44) Accepted Journal Date : 1999.11.04

(71) Applicant(s)
ResMed Limited

(72) Inventor(s)
Phillip Rodney Kwok

(74) Agent/Attorney
SPRUSON and FERGUSON,GPO Box 3898,SYDNEY NSW 2001

(56) Related Art
GB 1395391
CA 1039144

A MASK AND A VENT ASSEMBLY THEREFOR

ABSTRACT

A mask (10) for use with a system for supplying breathable gas pressurised above atmospheric pressure to a human or animal's airways. The mask (10) includes a
5 mask shell (12) which is, in use, in fluid communication with a gas supply conduit (30),
and a gas washout vent assembly (20). At least the region of the mask shell (12) or
conduit (30) surrounding or adjacent the vent assembly is formed from a relatively
flexible elastomeric material.

(Fig. 1)

AUSTRALIA

PATENTS ACT 1990

COMPLETE SPECIFICATION

FOR A STANDARD PATENT

ORIGINAL

Name and Address
of Applicant:

ResMed Limited
82 Waterloo Road
North Ryde New South Wales 2113
AUSTRALIA

Actual Inventor(s):

Phillip Rodney Kwok

Address for Service:

Spruson & Ferguson, Patent Attorneys
Level 33 St Martins Tower, 31 Market Street
Sydney, New South Wales, 2000, Australia

Invention Title:

A Mask and a Vent Assembly Therefor

ASSOCIATED PROVISIONAL APPLICATION DETAILS

[31] Application No(s)
P05045

[33] Country
AU

[32] Application Date
10 February 1997

The following statement is a full description of this invention,
including the best method of performing it known to me/us:-

A MASK AND A VENT ASSEMBLY THEREFOR

FIELD OF THE INVENTION

The present invention relates to a mask and a vent assembly therefor.

5 The mask and vent assembly according to the invention have been developed primarily for the venting of washout gas in the application of continuous positive airway pressure (CPAP) treatment in conjunction with a system for supplying breathable gas pressurised above atmospheric pressure to a human or animal. Such a system is used, for example, in the treatment of obstructive sleep apnea (OSA) and
10 similar sleep disordered breathing conditions. However, the invention is also suitable for other purposes including, for example, the application of assisted ventilation or respiration.

 The term "mask" is herein intended to include face masks, nose masks, mouth-
masks, nasal pillows, appendages in the vicinity of any of these devices and the like.

15

BACKGROUND OF THE INVENTION

 Treatment of OSA by CPAP flow generator systems involves the continuous delivery of air (or other breathable gas) pressurised above atmospheric pressure to a patient's airways via a conduit and a mask.

20 For either the treatment of OSA or the application of assisted ventilation, the pressure of the gas delivered to a patient can be at a constant level, bi-level (ie. in synchronism with patient inspiration and expiration) or autosetting in level to match therapeutic need. Throughout this specification the reference to CPAP is intended to incorporate a reference to any one of, or combinations of, these forms of pressure
25 delivery.

 The masks used in CPAP treatment generally include a vent for washout of the gas to atmosphere. The vent is normally located in the mask or in the gas delivery conduit adjacent the mask. The washout of gas through the vent is essential for removal of exhaled gases from the breathing circuit to prevent carbon dioxide "re-

breathing" or build-up, both of which represent a health risk to the mask wearer. Adequate gas washout is achieved by selecting a vent size and configuration that will allow a minimum safe gas flow at the lowest operating CPAP pressure, which, typically can be as low as around 4 cm H₂O for adults and 2 cm H₂O in paediatric applications.

5 Prior art masks are generally comprised of a rigid plastic shell which covers the wearer's nose and/or mouth. A flexible or resilient rim (or cushion) is attached to the periphery of the shell which abuts and seals against the wearer's face to provide a gas-tight seal around the nose and/or mouth.

10 A prior art washout vent utilized one or more holes or slits in the rigid shell or in a rigid portion of the delivery conduit to allow the washout gas to vent to atmosphere. In some masks, the holes or slits were formed during the moulding process. In others, they were drilled or cut as a separate step after the shell or conduit had been moulded.

15 The flow of gas out the holes or slits in the shell or conduit to atmosphere creates noise and turbulence at the hole or slit outlet as the delivered gas, and upon expiration, the patient-expired gas (including CO₂) exits. Bi-level and autosetting gas delivery regimes tend to generate more noise than a constant level gas delivery regime. This is thought to be due to the extra turbulence created by the gas accelerating and decelerating as it cycles between relatively low and relatively high pressures. The
20 noise adversely affects patient and bed-partner comfort.

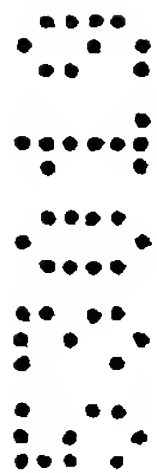
Another prior art vent included hollow rivets or plugs manufactured from stainless steel or other rigid materials attached to openings in the rigid shell. The outer edges of the rivets were rounded to help reduce noise. However, this approach was expensive, required an extra production step and did not prove effective in reducing
25 noise.

Another approach to reduce noise involved the use of sintered filters at the gas outlet of the mask shell. However, the filters were prone to blocking, especially in the presence of moisture. Accordingly, sintered filters were impractical for use in CPAP treatment as they were easily blocked by the moisture from the patient's respiratory

system or humidifiers or during the necessary regular cleaning of the mask and associated componentry.

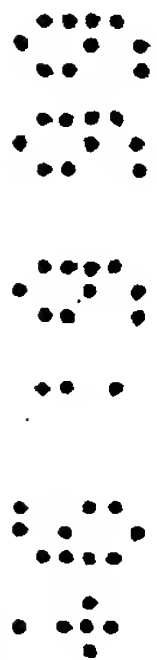
Foam filters wrapped around the air outlets in the shell were also attempted. However, they also suffered from the disadvantages of being prone to blocking,
5 difficult to clean and requiring constant replacement.

Remote outlet tubes have been used to distance the noise source from the patient. However, these tubes are difficult to clean, are prone to entanglement by the patient and/or their bed partner and suffer the further disadvantage that a volume of exhausted gas is retained in the tube adjacent the mask.



10 It is an object of the present invention to substantially overcome or at least ameliorate the prior art disadvantages and, in particular, to reduce the noise generated by gas washout through a mask.

SUMMARY OF THE INVENTION



15 Accordingly, the invention, in a first aspect, discloses a mask for use with a system for supplying breathable gas pressurised above atmospheric pressure to a human or animal's airways, the mask includes a mask shell which is, in use, in fluid communication with a gas supply conduit, and a gas washout vent assembly, wherein the mask shell and/or conduit is formed from a relatively rigid material and the vent
20 assembly is an insert formed from a relatively flexible elastomeric material and is attachable to the mask shell or conduit.

In a second aspect, the invention discloses a vent assembly for the washout of gas from a mask shell or conduit used with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal, the mask or conduit
25 being formed from a relatively rigid material, wherein the vent assembly is an insert of relatively flexible elastomeric material and is attachable to the mask shell or conduit.

The insert preferably has at least one orifice therethrough.

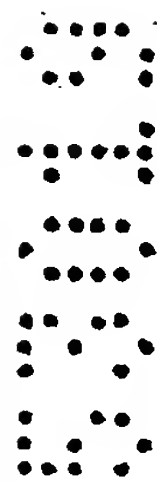


In a preferred form, the mask shell and/or the conduit is formed from polycarbonate and the insert is formed from Silastic™ or Santoprene™.

Desirably, the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

5 The insert preferably includes a groove around its periphery, the groove adapted to locate the insert against a correspondingly sized rim of an opening formed in the mask shell or conduit.

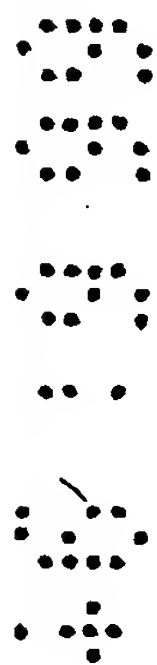
In other embodiments, the insert is substantially circular, triangular, cross or peanut shaped.



10 The mask shell and/or the conduit can desirably also include one or more inserts.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of
15 examples only, with reference to the accompanying drawings in which:



20

Fig. 1 is a perspective view of a first embodiment;

Fig. 2 is a perspective view of a second embodiment;

Fig. 3 is a perspective view of a third embodiment;

Fig. 4 is a perspective view of a fourth embodiment;

Fig. 5 is a perspective view of a fifth embodiment;

Fig. 6 is a perspective view of a sixth embodiment;

Fig. 7 is a perspective view of a seventh embodiment;

Fig. 8 is a partial cross-sectional view of the first embodiment along the line 8-8 of Fig. 1;

25

Fig. 9 is a perspective view of an eighth embodiment;

Fig. 10 is a plan view of the insert of the third embodiment;



Fig. 11 is a cross-sectional view of the third embodiment insert along the line 11-11 of Fig. 10; and

Fig. 12 is a partial cross-sectional view of the third embodiment insert along the line 12-12 of Fig. 10.

5

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring firstly to Fig. 1, there is shown a mask 10 for use with a system (not shown) for supplying breathable gas pressurised above atmospheric pressure to a human or animal's airways. The mask includes a rigid plastics shell 12 having an inlet tube 14 for connection to a supply conduit to communicate breathable gas from a flow generator (not shown) to the nasal passages of the mask wearer. The mask shell 12 also includes a flexible sealing membrane 16 which is used to provide a gas tight seal between the face of the wearer and the interior of the shell 12. The shell 12 also includes lugs 18 for connecting the mask 10 to a head strap (not shown) to retain the mask in place.

10
15
20
The mask includes a Silastic™ insert 20 through which is provided an orifice 22 for gas washout. As best shown in Figure 8, the insert 20 has a recess or groove 24 around its periphery. A correspondingly sized opening 26 bounded by a rim 28 is provided in the shell 12 to enable the insert 20 to be retained in place in the fashion of a grommet. The opening 26 can be moulded in the shell 12 or drilled or punched as a post-moulding step. The flexibility of the Silastic™ allows the insert 20 to be initially squeezed through the opening 26 before resiliently expanding to the configuration shown in Fig. 8 and engaging the rim 28.

Figs. 2 to 7 show further embodiments in which corresponding reference numerals are used to indicate like features. In all these embodiments the insert 20 has an external groove or recess 24 which engages the rim 28 of a corresponding shaped opening 26 in the mask shell 12 to retain the insert 20 in place.

In the embodiment shown in Figs. 2 to 5 and 7 the insert 20 includes more than one orifice 22. In the embodiment shown in Fig. 6, two inserts 20 are provided in the shell 12.

In the embodiment shown in Fig. 9, the insert 20 is provided in a gas supply conduit 30.

Figs. 10 to 12 show the insert 20 of the third embodiment of Fig. 3. The dimensions 32, 34, 36, 38, 40, 42 and 44 are approximately diameter 1.73 mm, diameter 3.30 mm, 28.80 mm, 19.00 mm, 1.20 mm, 1.20 mm and 3.60 mm respectively.

The side 44 of the insert 20 faces the patient's face in use and the side 46 faces atmosphere.

The mask shell 12 is manufactured from polycarbonate. Other rigid plastics materials can equally be used. The insert 20 can be manufactured from an elastomer sold as Silastic™ (produced by the Dow Corning Corporation) or a thermoplastic elastomer sold as Santoprene™ (produced by Monsanto). Other flexible elastomeric materials can be used also.

The mask 10 produces less noise than an identical mask having a similar sized and shaped orifice(s) formed directly in the mask shell 12 instead of formed in the flexible insert 20. It is thought that the noise reduction occurs due to the flexible insert 20 damping vibrations caused by air passage through the orifice(s) 22 which produce vibrations or similar in the mask shell 12.

A prototype of the embodiment of the invention shown in Figure 3 has been tested over a range of constant and bi-level CPAP treatment pressures. For comparison purposes, an identical mask to that shown in Fig. 3 but formed entirely from polycarbonate and having six identical arcuately spaced holes 22 drilled directly through the mask shell was also tested. In both masks the six holes had a diameter of 1.7 mm. The results of the test are summarised in the Tables below:

TABLE 1

Constant level gas delivery

Pressure (cm H ₂ O)	Noise levels 1m from mask (dBA)	
	With flexible insert	Without flexible insert
4	26.8	35.2
10	33.4	43.1
18	39.3	49.2

TABLE 2

Bi-level gas delivery

Pressure (cm H ₂ O)	Noise levels 1m from mask (dBA)	
	With flexible insert	Without flexible insert
5 - 10	30.8 - 38.5	37.2 - 43.0
10 - 15	38.6 - 43.7	42.9 - 47.9

As the results show, the mask shown in Figure 3 produced less radiated noise than a similar mask not including the flexible elastomeric insert 20 representing a significant advantage in terms of the comfort of the mask wearer and their bed partner.

In addition to the noise reduction discussed above, the masks 10 possesses other advantages over those of the prior art. Firstly, the insert 20 is very easy to install into the mask shell 12 during either assembly of the mask which, is often supplied in kit form, or before and after cleaning which is regularly required and often carried out in the home environment. Secondly, the mask shell 12 may be produced with a single

size of opening 26 and provided with a range of different inserts 20 which allows the outlet size to be "tuned" to give an optimum gas washout rate for a particular patient's treatment pressure level.

Although the invention has been described with reference to specific examples,
it will be appreciated by those skilled in the art, that the invention may be embodied in
many other forms.

A 10x10 grid of dots forming the number 10. The number 1 is formed by a vertical column of 10 dots. The number 0 is formed by a horizontal row of 10 dots, with the middle two dots of the row missing, creating a central gap.

The claims defining the invention are as follows:

1. A mask for use with a system for supplying breathable gas pressurised above atmospheric pressure to a human or animal's airways, the mask includes a mask shell which is, in use, in fluid communication with a gas supply conduit, and a gas washout vent assembly, wherein the mask shell and/or conduit is formed from a relatively rigid material and the vent assembly is an insert formed from a relatively flexible elastomeric material and is attachable to the mask shell or conduit.
2. A mask as claimed in claim 1, wherein the mask shell and/or conduit is formed from polycarbonate and the insert is formed from Silastic™ or Santoprene™.
3. A mask as claimed in claim 1 or 2, wherein the insert has at least one orifice therethrough.
4. A mask as claimed in any one of claims 1 to 3, wherein the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.
5. A mask as claimed in any one of claims 1 to 3, wherein the insert is substantially circular, triangular, cross or peanut shaped.
6. A mask as claimed in any one of claims 1 to 5, wherein the insert includes a groove around its periphery, the groove adapted to locate the insert against a correspondingly sized rim of an opening formed in the mask shell or conduit.
7. A mask as claimed in any one of claims 1 to 6, wherein the mask shell or the conduit includes a plurality of said inserts.
8. A vent assembly for the washout of gas from a mask shell or conduit used with a system for supplying breathable gas pressurized above atmospheric pressure to a human or animal, the mask or conduit being formed from a relatively rigid material, wherein the vent assembly is an insert of relatively flexible elastomeric material and is attachable to the mask shell or conduit.
9. A vent assembly as claimed in claim 8, wherein the mask shell and/or the conduit is formed from polycarbonate and the insert is formed from Silastic™ or Santoprene™.



10. A vent assembly as claimed in claim 8 or 9, wherein the insert has at least one orifice therethrough.

11. A vent assembly as claimed in any one of claims 8 to 10, wherein the insert is substantially crescent-shaped and includes a plurality of orifices therethrough.

5 12. A vent assembly as claimed in any one of claims 8 to 10, wherein the insert is substantially circular, triangular, cross or peanut shaped.

13. A vent assembly as claimed in any one of claims 8 to 12, wherein the insert includes a groove around its periphery, the groove adapted to locate the insert against a correspondingly sized rim of an opening formed in the mask shell or conduit.

10 14. A mask substantially as described herein with reference to: Figs. 1 and 8; Fig. 2; Figs 3 and 10 to 12; Fig. 4; Fig. 5, Fig. 6; or Fig. 7 of the accompanying drawings.

15 15. A vent assembly substantially as described herein with reference to: Figs. 1 and 8; Fig. 2; Figs 3 and 10 to 12; Fig. 4; Fig. 5, Fig. 6; or Fig. 7 of the accompanying drawings.

DATED this Third Day of September, 1999

ResMed Limited

Patent Attorneys for the Applicant/Nominated Person

SPRUSON & FERGUSON



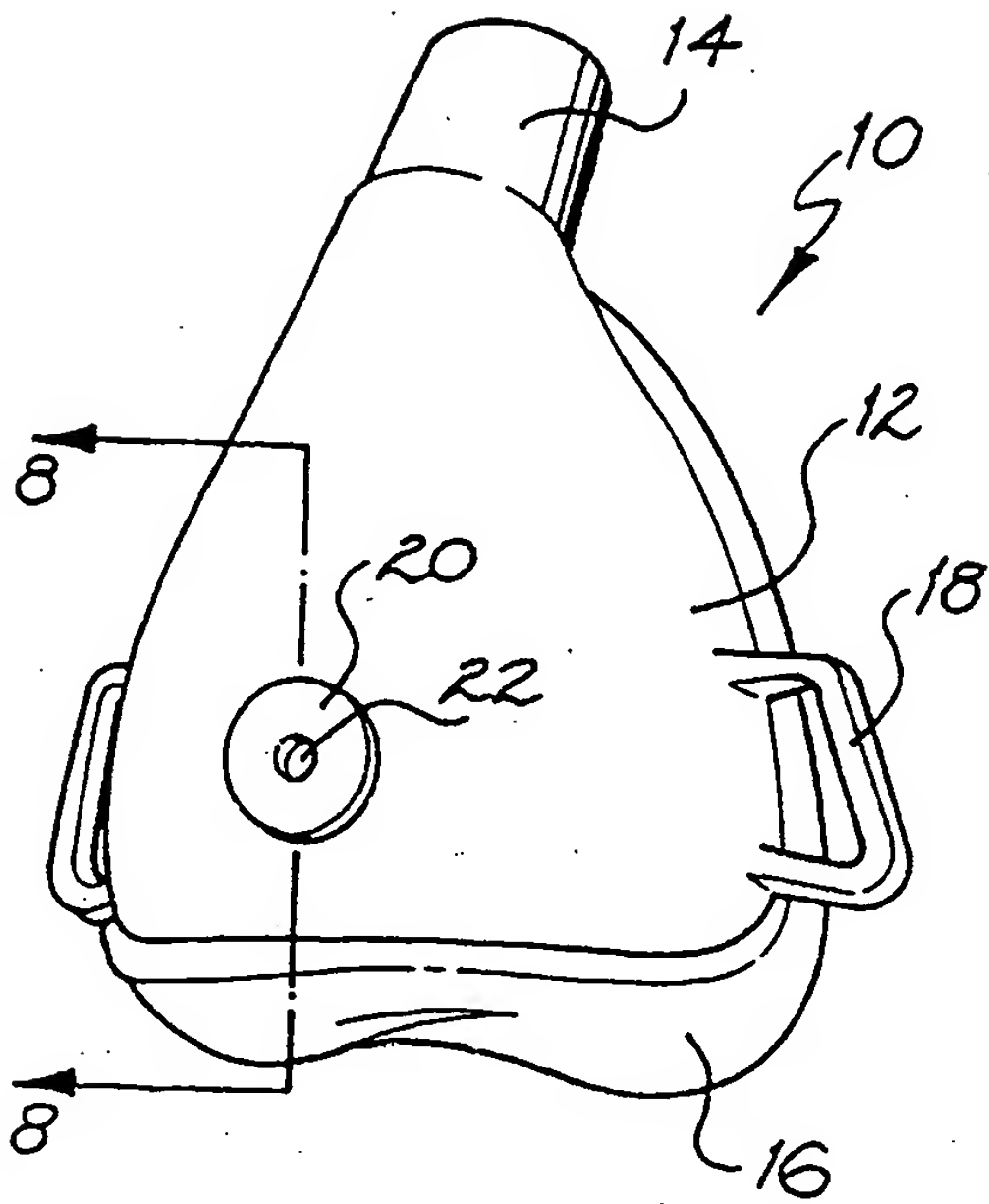


FIG. 1

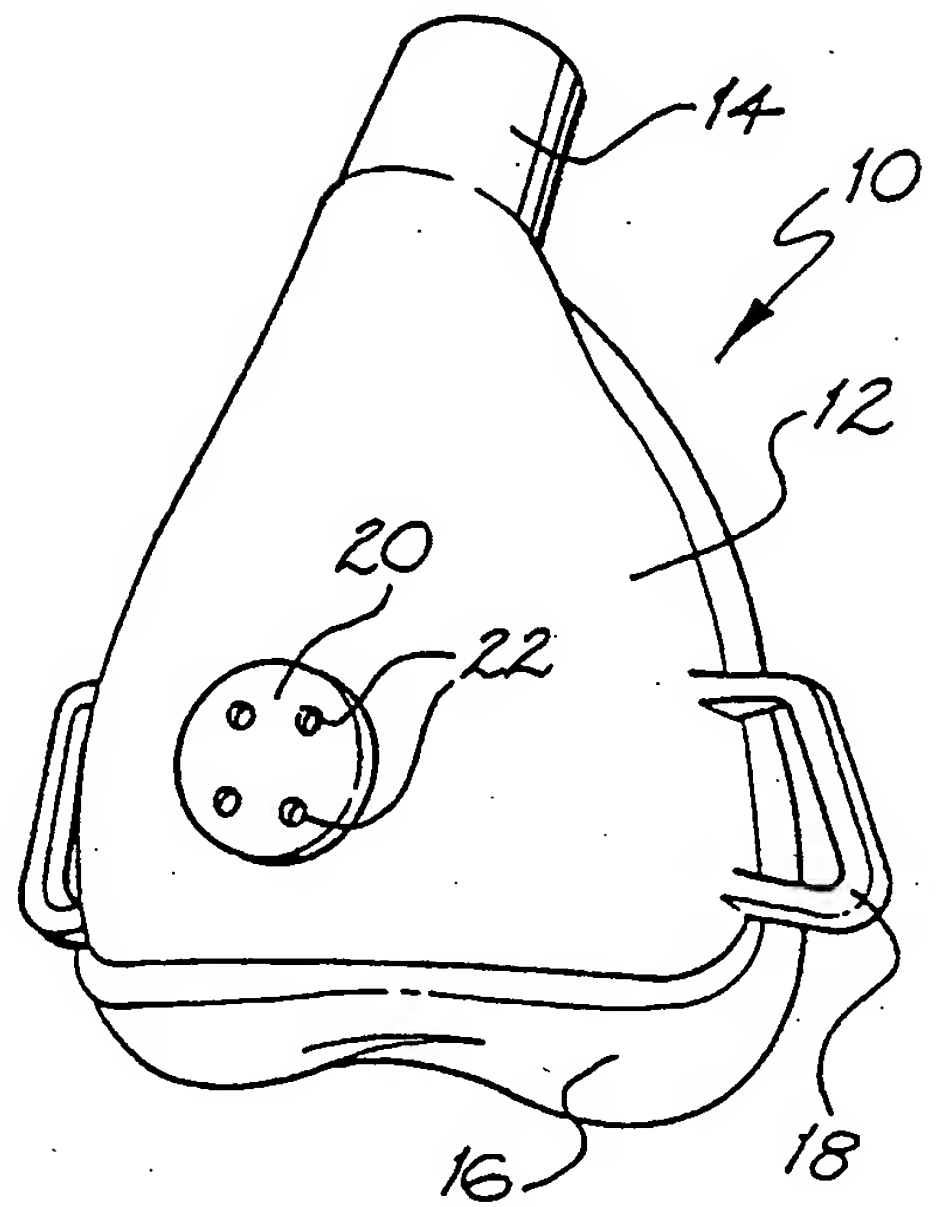


FIG. 2

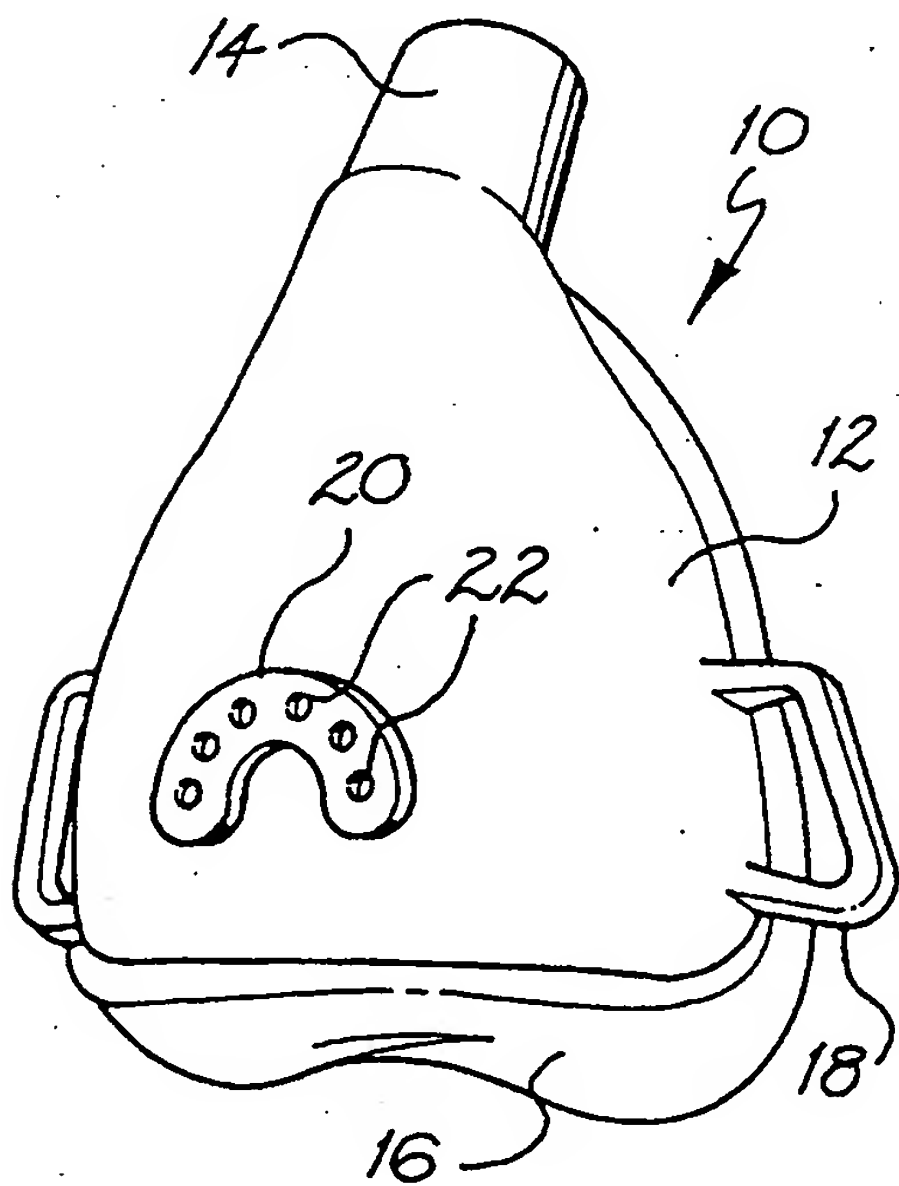


FIG. 3

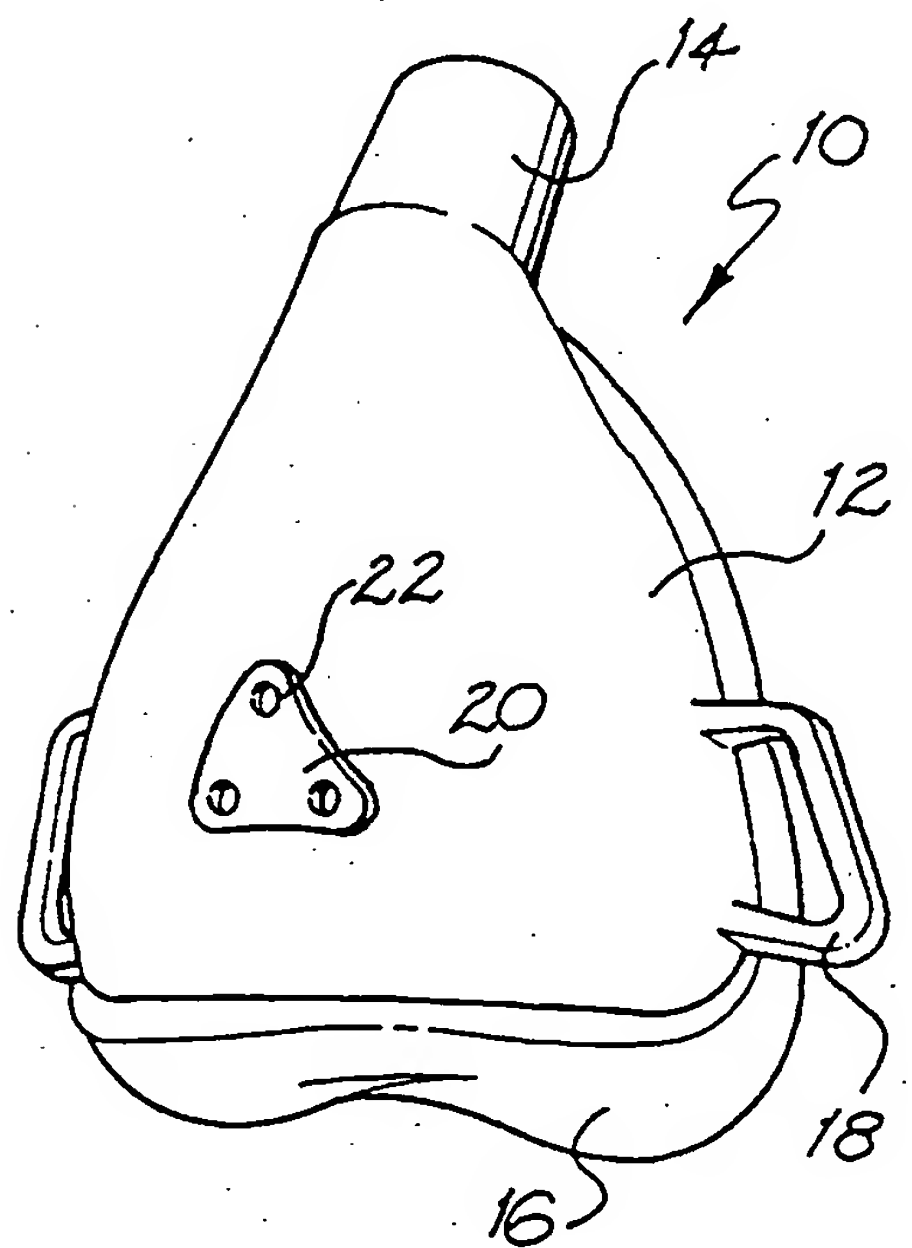


FIG. 4

2
2
8
0

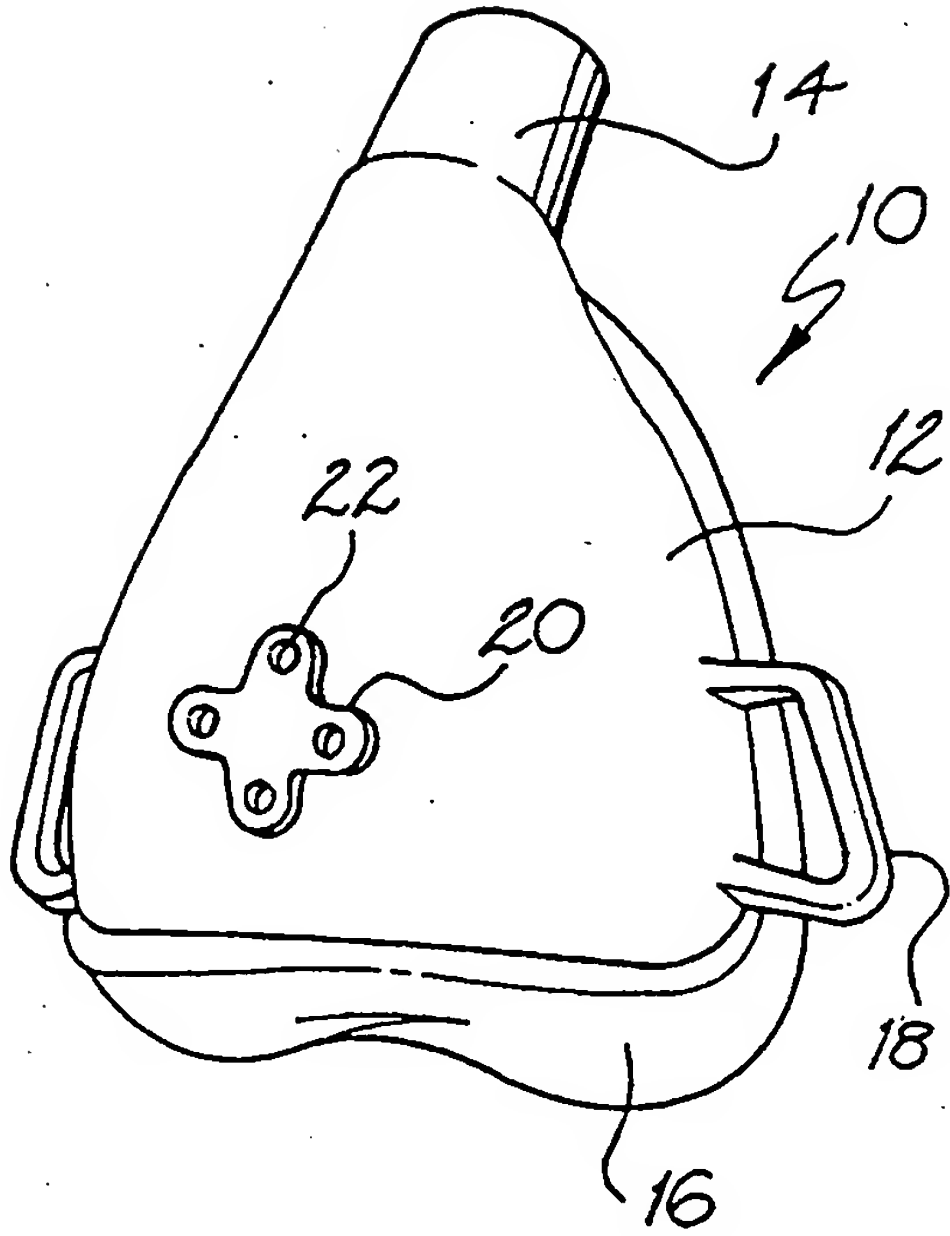


FIG. 5

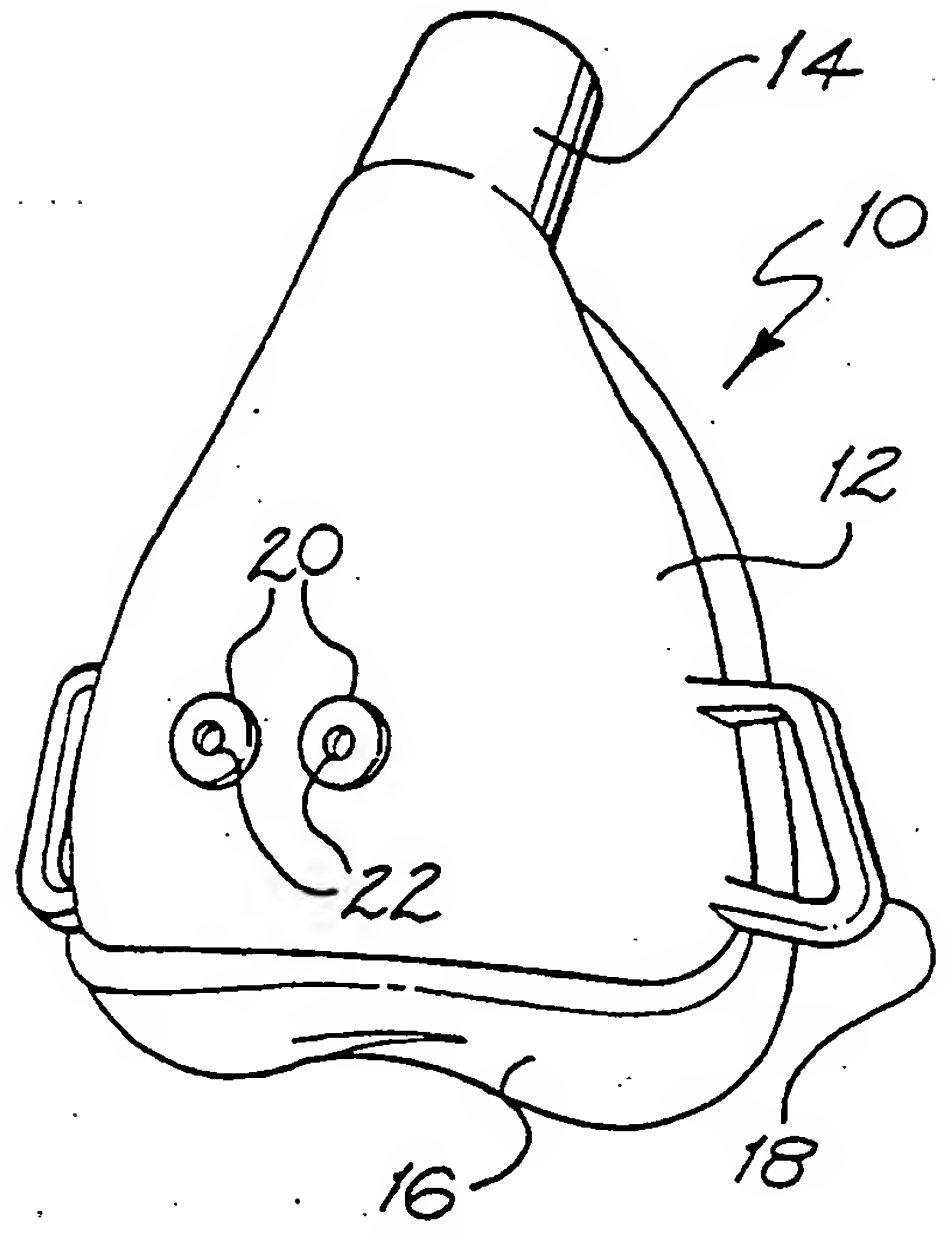


FIG. 6

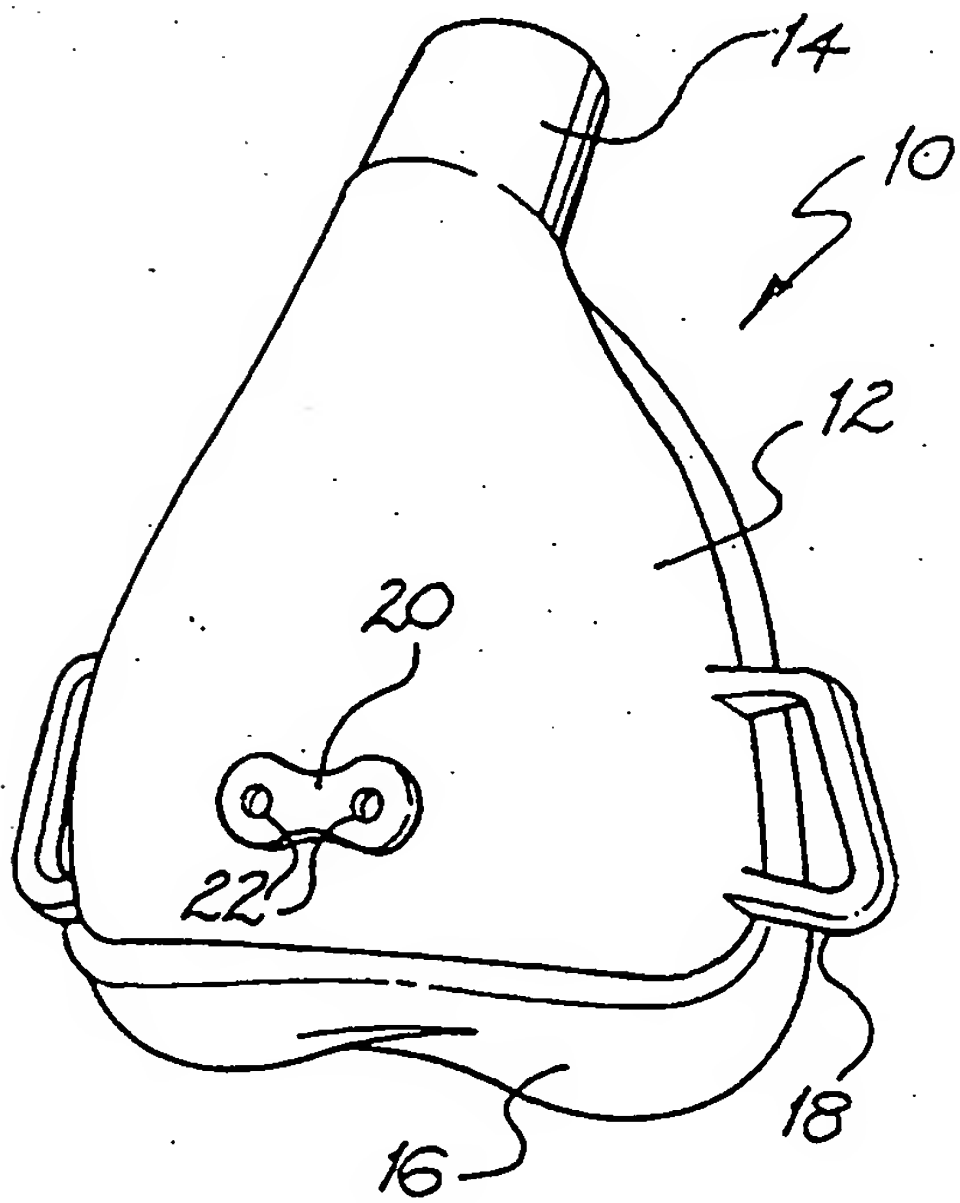


FIG. 7

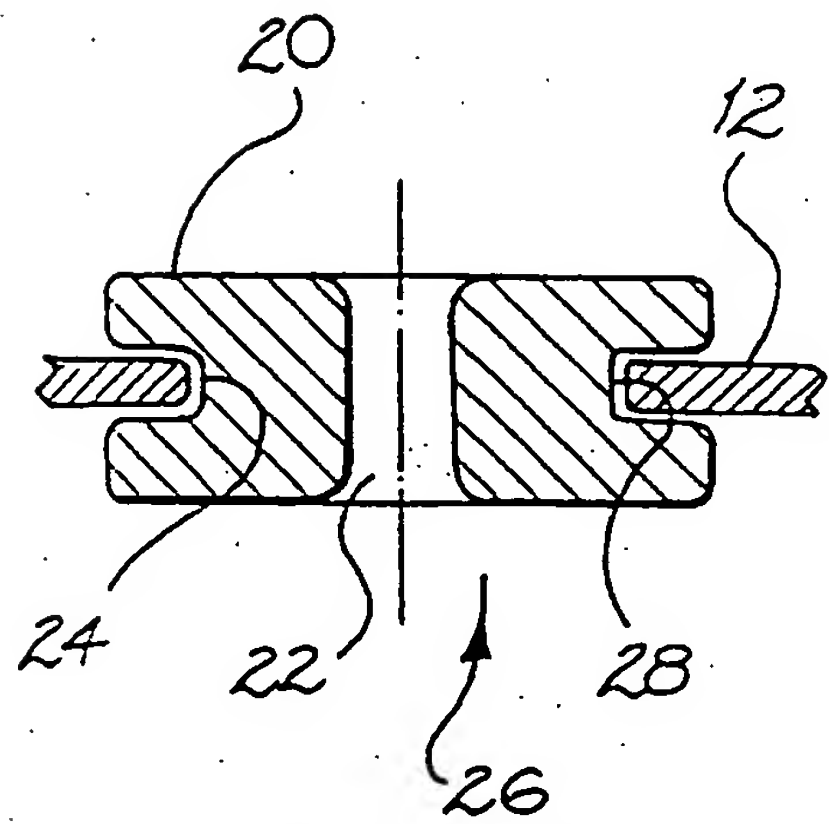


FIG. 8

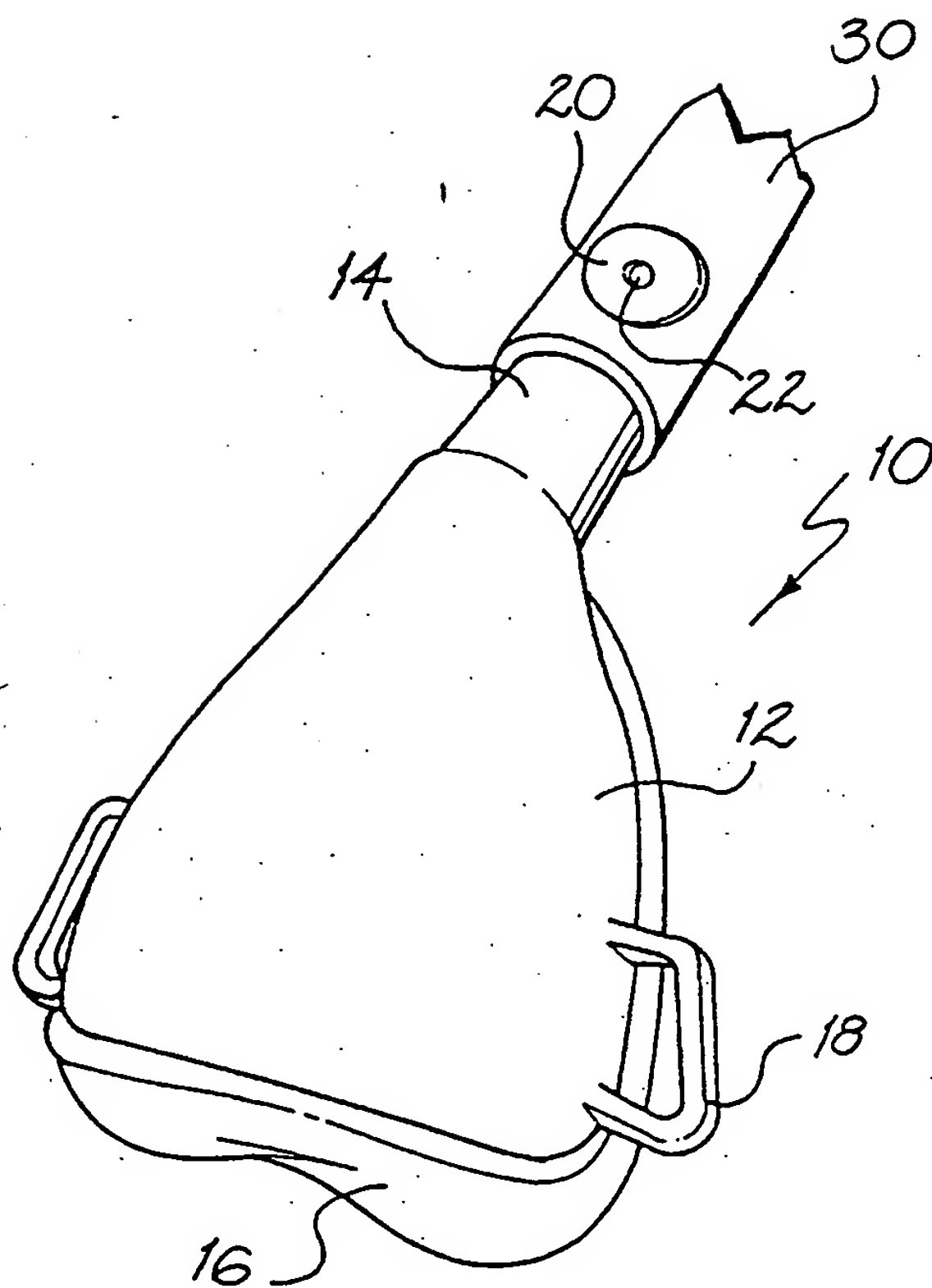


FIG. 9

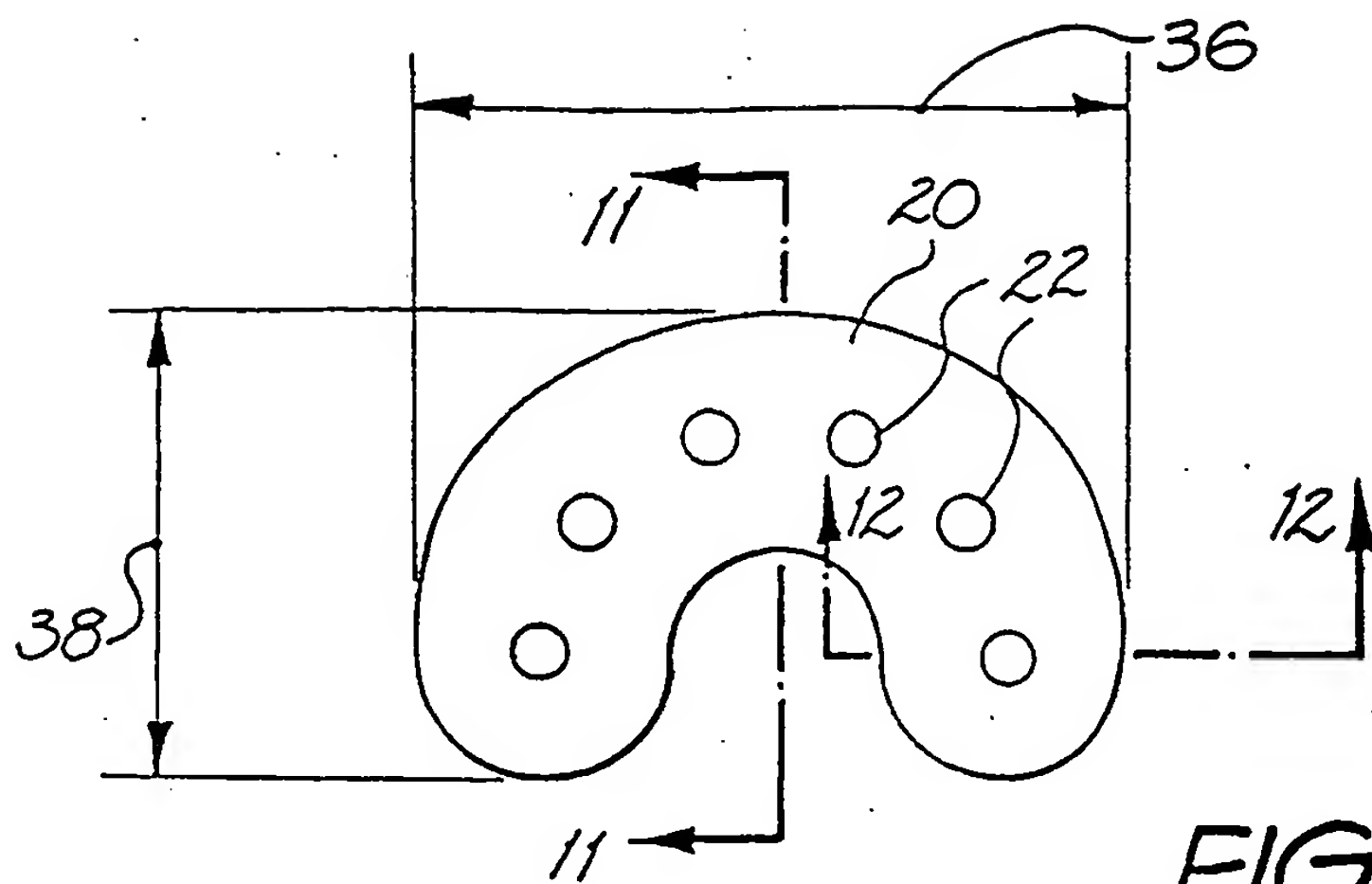


FIG. 10

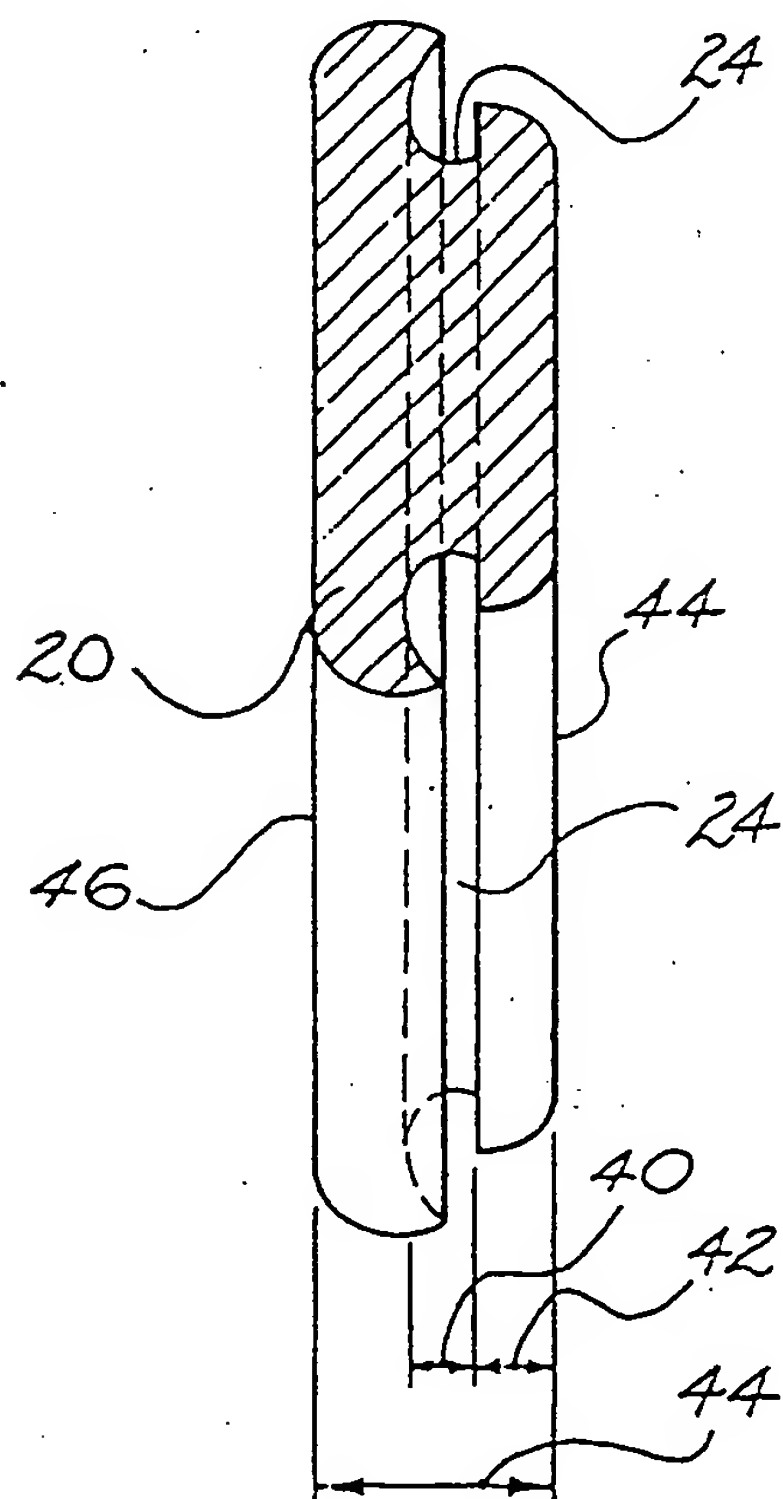


FIG. 11

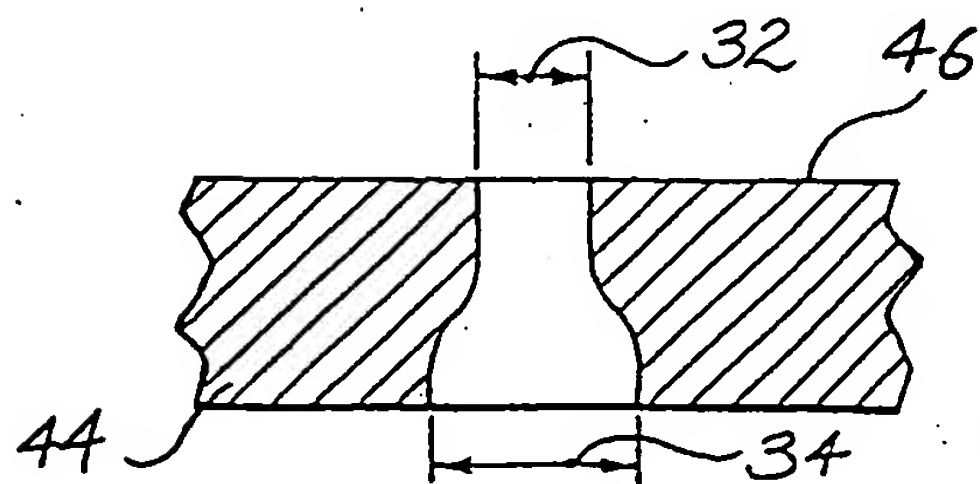


FIG. 12